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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,756

04/21/2006

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EXAMINER

DOE, SHANTA G

ART UNIT

PAPER NUMBER

1775

NOTIFICATION DATE

DELIVERY MODE

07/13/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/576,756	<b>Applicant(s)</b> SHIGESADA ET AL.	
	<b>Examiner</b> SHANTA G. DOE	<b>Art Unit</b> 1775	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-17,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-17 is/are allowed.
- 6) ☒ Claim(s) 1,2,5,22 and 23 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Allowable Subject Matter***

1. The indicated allowability of claim 1 and its dependent claims and claims 22 and 23 is withdrawn. See rejections below.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 22, the claim recites "...resin hydrophilicity of the end face and the outer wall surface of the discharge part is enhanced"; However, it is unclear to the examiner what kind of enhancement and how the hydrophilicity of end face and outer wall of the discharge part is enhanced.

Regarding claim 23, the claim recites "...the bubbles". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al (US 6,159,368).

Regarding claim 1, Moring discloses a cartridge ((12) called minicolumn of a column plate) for nucleic acid separation and purification which comprises: a cylindrical main body formed of a cylindrical part (12) and a bottom part having an opening; and a nucleic acid-adsorptive porous membrane (8) held on the bottom part, a rim part of the

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nucleic acid-adsorptive porous membrane being held by a molding material forming the cylindrical part of the cylindrical main body (col. 12 lines 6-7 states that the device is made by injection molding ) and the rim part of the nucleic acid-adsorptive porous membrane is compressed so that voids in the rim part of the membrane disappear( col. 16 lines 35-42 discloses that filter element is compressed between the shoulder and rim 16a in a manner effective to secure the filter element in place and to press the circumferential side edge against the inner surface of the column in order to prevent leakage, based on the disclosure it is inherent that the voids disappear since there would be leakage if the voids were still present) which cartridge is produced by: inserting a bottom member and the nucleic acid-adsorptive porous membrane into a cavity of an injection molding die wherein the nucleic acid-adsorptive porous membrane is placed in the bottom member providing the bottom part which is one of two parts that sandwich and hold the nucleic acid-adsorptive porous membrane; and injecting the molding material into the cavity to form the cylindrical part of the cylindrical main body wherein a portion forming the cylindrical part which is the other of the two parts that sandwich and hold the nucleic acid-adsorptive porous membrane is integrated with the bottom member while the nucleic acid-adsorptive porous membrane is sandwiched and held between the cylindrical part and the bottom part (see abs, fig 4-6, col.4 lines 12-15, 47-49, 65- col. 5 line 5; col. 6 lines 15-20 ,col. 12 lines 6-7; col. 15 – col. 17). Moring fails to specifically disclose that the cylindrical part is integrally formed with the bottom part and nucleic acid-adsorptive porous membrane.

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However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the cylindrical part be integrally formed with the bottom part and nucleic acid-adsorptive porous membrane, since it has been held that forming in one piece an article which has formerly been formed in two (or more) pieces and put together involves only routine skill in the art.

Regarding claim 2, Moring discloses the cartridge for nucleic acid separation and purification according to claim 1, wherein the bottom member further comprises a cylindrical discharge part (see fig 4&5), the end part of funnel shaped piece of (16)) communicating with the opening of the bottom part.

Regarding claim 5, Moring discloses the cartridge for nucleic acid separation and purification according to claim 3, wherein the rim part of the nucleic acid-adsorptive porous membrane is compressed. Moring fails to disclose that the membrane is compressed to a thickness of 10% to 70% of an initial thickness.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the membrane be compressed to a thickness of 10 -70 % of an initial thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

***Allowable Subject Matter***

9. Claims 6-17 are allowed.

Regarding claim 6 and its dependent claim, the prior art alone or in combination **fails** to disclose a method for producing a cartridge for nucleic acid separation and purification: the method comprising a step of placing the nucleic acid absorptive porous membrane on the bottom part provided in the bottom member and placing the bottom member and the membrane in a cavity of an injection molding die; a step of pressing a core pin to the membrane while holding the membrane with a rim part of the membrane protruding from the periphery of an end face of the core pin and closing the injection molding die; a step of injecting a molding material into the cavity forming the cylindrical part of the cylindrical main body and at the same time sandwiching and holding the rim part of the membrane between the molding material and the bottom part and step of removing a casting from the injection molding die.

Regarding 12-17, the prior art **fails** to disclose the cartridge having a protrusion where in the top part of each protrusion slopes down to the discharged part in a radial direction of the bottom part.

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The closest prior art to the applicant invention claimed in claims 6-17 is Moring et al (US 6,159,368).

The Moring reference discloses a cartridge for nucleic acid separation and purification where the cartridge comprises a cylindrical main body formed of a cylindrical part and a bottom part having an opening and a nucleic acid adsorptive porous membrane held on the bottom part wherein the device is made by injection molding (see Moring abs, fig 4-6, col.4 lines 12- 15, 47-49, 65- col. 5 line 5; col. 6 lines 15-20 ,col. 12 lines 6-7; col. 15 – col. 17. However, the reference **fails** to disclose the specifics of the method by which the device is made and hence the reference **fails** to disclose the steps of the method as is claimed by the applicant in claim 6 or a cartridge comprising a protrusion wherein the top part of each protrusion slopes down to the discharged part of the cartridge in a radial direction of the bottom part .

10. Claims 22 and 23 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Regarding claim 22, the prior art **fails** to disclose the cartridge for nucleic acid separation and purification which comprises all of the instantly claimed features.



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Regarding claim 23, the prior art **fails** to disclose the cartridge for nucleic acid separation and purification wherein at least one lug member for guiding bubbles is provided on an end face of the discharge part.

### ***Response to Arguments***

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G. D./  
Examiner, Art Unit 1775

/Michael A Marcheschi/  
Supervisory Patent Examiner, Art  
Unit 1775